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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,907	01/28/2002	Ernest P. Brody	LL11.12-0051	5175

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,907	BRODY, ERNEST P.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Groups 1-4, drawn to methods of fractionating and processing proteinaceous material:

1. Claims 1-25, drawn to a first method – a method of fractionating a first proteinaceous material via heating to an elevated temperature, classified in class 514, subclass 2, for example.

2. Claims 1-25, drawn to a second method – a method of fractionating a second proteinaceous material via pH greater than about 7, classified in class 514, subclass 2, for example.

3. Claims 26-45, drawn to a third method – a method of processing a proteinaceous material comprising a κ-casein macropeptide, classified in class 514, subclass 21, for example.

4. Claims 46-51, drawn to a fourth method – a method of fractionating a proteinaceous material comprising a κ-casein macropeptide, classified in class 514, subclass 21, for example.

II. Groups 5 and 6, drawn to products:

5. Claims 52-56, drawn to a first product – a polymerized protein material, classified in class 530, subclass 350, for example.

6. Claims 57-59, drawn to a second product – a κ-casein macropeptide-enriched powder, classified in class 424, subclass 489, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I (distinct processes) and II (distinct products) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, as evidenced by the claims themselves, the various and distinct protein materials of Group IV-V can be made via one or more of the distinct preparatory processes of Groups I-III.

The methods of Groups 1-4 are distinct each from the other - i.e., they are directed to different inventions which are not connected in design, operation, and/or effect - including each method having different and distinct preparatory steps therein. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The products of Groups 5 and 6 are distinct each from the other. For example, the product of Group 5 is a polymerized protein material having several physical properties which are not necessarily shared by the product of Group 6; whereas the

product of Group 6 is a κ-casein macropeptide-enriched powder having various physical properties which are not necessarily shared by the product of Group 5.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and the search required for one Group is not necessarily required for the other Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If Applicant elects from Group 1 or 2:

Claims 1-22 and 24 are generic to a plurality of disclosed patentably distinct species comprising κ-casein macropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 23 and 25 are generic to a plurality of disclosed patentably distinct species comprising glycomacropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-5 and 9-25 are generic to a plurality of disclosed patentably distinct species comprising an elevated temperature. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising a heat labile protein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-13 and 22-25 are generic to a plurality of disclosed patentably distinct species comprising a filtration membrane. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising a third proteinaceous material. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising a fourth proteinaceous material. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 2 and 3 are generic to a plurality of disclosed patentably distinct species comprising polymers containing:

A) β-lactoglobulin

B) α-lactalbumin

C) β-lactoglobulin and α-lactalbumin

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 4 and 23-25 are generic to a plurality of disclosed patentably distinct species comprising glycomacropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising polymerized β-lactoglobulin or polymerized α-lactalbumin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 6 is generic to a plurality of disclosed patentably distinct species comprising temperatures greater than about 175 ºF. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 7 is generic to a plurality of disclosed patentably distinct species comprising temperatures at least greater than about 180 ºF. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 8 is generic to a plurality of disclosed patentably distinct species comprising temperatures less than about 140 ºF. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 9-13 are generic to a plurality of disclosed patentably distinct species comprising a polymerized protein powder. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 14 and 15 are generic to a plurality of disclosed patentably distinct species comprising a microfiltration membrane. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 15 is generic to a plurality of disclosed patentably distinct species comprising pore diameter in the range of about 0.02 microns to less than about 2 microns. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 22 is generic to a plurality of disclosed patentably distinct species comprising a derivative of the filtration permeate. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects from Group 3 (Claims 26-45):

Claims 26-35 and 40-45 are generic to a plurality of disclosed patentably distinct species comprising κ-casein macropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 36-39 are generic to a plurality of disclosed patentably distinct species comprising glycomacropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 30 is generic to a plurality of disclosed patentably distinct species comprising Brookfield viscosity of at least about 6,000 centipose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 31 is generic to a plurality of disclosed patentably distinct species comprising Brookfield viscosity of at least about 10,000 centipose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 34 is generic to a plurality of disclosed patentably distinct species comprising concentration of κ-casein macropeptide at least about two times greater. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising concentration of κ-casein macropeptide at least about 35 weight percent. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising concentration of glycomacropeptide at least about two times greater. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising concentration of glycomacropeptide at least about 35 weight percent.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects from Group 4 (Claims 46-51):

Claims 46-51 are generic to a plurality of disclosed patentably distinct species comprising κ-casein macropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 46-51 are generic to a plurality of disclosed patentably distinct species comprising a pH. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 46-51 are generic to a plurality of disclosed patentably distinct species comprising an elevated temperature. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 46-51 are generic to a plurality of disclosed patentably distinct species comprising a heated holding period. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 46-49 and 51 are generic to a plurality of disclosed patentably distinct species comprising a heat labile protein. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 46-51 are generic to a plurality of disclosed patentably distinct species comprising portions of at least about 80 weight percent. Applicant is required under 35

U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 50 is generic to a plurality of disclosed patentably distinct species comprising β-lactoglobulin or α-lactalbumin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects Group 5 (Claims 52-56):

Claim 52-56 is generic to a plurality of disclosed patentably distinct species comprising polymers of β-lactoglobulin or α-lactalbumin. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 54 and 56 are generic to a plurality of disclosed patentably distinct species comprising Brookfield viscosity of at least about 6,000 centipose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claim 55 is generic to a plurality of disclosed patentably distinct species comprising Brookfield viscosity of at least about 10,000 centipose. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If Applicant elects Group 6 (Claims 52-56):

Claims 57-60 are generic to a plurality of disclosed patentably distinct species comprising κ-casein macropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 59 and 60 are generic to a plurality of disclosed patentably distinct species comprising glycomacropeptide. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 57 and 59 are generic to a plurality of disclosed patentably distinct species comprising ratios of at least about 0.7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Claims 58 and 60 are generic to a plurality of disclosed patentably distinct species comprising ratios of at least about 1. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

Andrew D. Kosar
12 May 2004

PATRICIA LEITH
PRIMARY EXAMINER